K120333
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MAY 25 2012

510(k) SUMMARY

Submitted by: Gambro Renal Products Inc.
1845 Mason Avenue
Daytona Beach, FL 32117

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Contact: Fei Law

Date Prepared: 05/21/2012

Trade Name: PrismaSATE

Common Name: Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT)
Ready to Use Sterile Dialysate

Classification Name: Dialysate Concentrate for Hemodialysis (Liquid or Powder) per 21 CFR 876.5820. The Product/Classification Code is KPO.

Equivalent Predicate: PrismaSATE Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT)
Gambro Renal Products, K013448

PrismaSATE Dialysis Solutions for Continuous Renal Replacement Therapy (CRRT)
Gambro Renal Products, K072908

B. Braun Modified Bicarbonate Dialysate
B. Braun, K052393

Device Description: Gambro PrismaSATE solutions are sterile dialysate solutions for use in Continuous Renal Replacement Therapy (CRRT) for the treatment of acute renal failure and in other cases necessitating fluid or solute removal, such as in the case of drug poisoning with dialyzable or filterable substances. The solutions are intended to be used in commercially available continuous renal replacement therapy machines as dialysate. A physician prescribes the chemical composition of the solution to be used. The solutions are sterile, and packaged in flexible bags.

Testing, and Recognized Standards: **Expiration Dating:** Stability studies for expiration dating are performed for Gambro PrismaSATE at controlled conditions, per an approved protocol and results have been provided.

Sterilization: Gambro PrismaSATE solutions are terminally sterilized using steam. The validation methods used follow ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 11138-3.

Biocompatibility: The primary packaging material for PrismaSATE solution was tested per Gambro's procedure for physico-chemical and biological evaluation and qualification of materials for medical devices and drug containers. Tests performed included selected physico-chemical tests and biological tests, and have been provided.

Intended Use: Gambro PrismaSATE solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.
CRRT is used for the treatment of acute renal failure and in other cases necessitating fluid or solute removal, such as in the case of drug poisoning with dialyzable or filterable substances. The solutions are perfused through the dialysis fluid

compartment of hemofilters/dialyzers. The dialysate is separated from the patient's blood by means of a semi-permeable membrane. Excess waste products, fluids and toxins found in the blood of a patient with acute renal failure pass through the membrane into the dialysate and eventually go to waste. The therapy is aimed at normalizing the blood.

Predicate Device Comparison: The modified PrismaSATE Dialysis Solutions for CRRT has the same intended use, indication for use, chemical concentration range, and packaging characteristics as the predicate devices. There are no significant technological changes. Based on the above, the device is substantially equivalent to the stated predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Fei Law
Quality and Regulatory Manager, US Solutions
Gambro Renal Products Inc.
1845 Mason Avenue
DAYTONA BEACH FL 32117

MAY 2 5 2012

Re: K120333
Trade/Device Name: PrismaSATE ™
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: May 8, 2012
Received: May 10, 2012

Dear Ms. Law:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K120333

Device Name: PrismaSATE ™

Indications For Use:

Gambro PrismaSate solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120333